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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Vargas, Jaime; et. al.
Assignee: Cardica, Inc.
Title: Incision Tensioning System and Method for Using the Same
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RESPONSE TO OFFICE ACTION

TECHNOLOGY CENTER R3700

Dear Sir:

In response to the restriction requirement of the Office Action of October 10, 2002, Applicants elect Invention I, without traverse. However, Applicants provisionally elect Species VII of Invention I, and expressly traverse the requirement to elect species. Applicants provisionally elect claims 1, 10-16, and 18 as reading on Species I. VII (11/15/02)

REASONS FOR TRAVERSE UNDER 37 CFR 1.143

Under 37 CFR 1.143, Applicants must provide the reasons for requesting reconsideration and withdrawal of the election of species requirement. Two reasons are provided below.

First, the Office Action set forth no reason for requiring election of species. MPEP 816 states that "[t]he particular reasons relied on by the examiner for holding that the inventions as claimed are...distinct should be concisely stated. A mere statement of conclusion is inadequate." (emphasis added). Additionally, the Office Action simply states

that “no claims are generic” as to each invention, while setting forth no support or explanation for this conclusory statement. By providing no reasons for requiring election of species, and by providing no reasons for finding that no claims in identified inventions I and II are generic, the Office Action fails to meet the standards set forth in the Manual of Patent Examining Procedure. Thus, the requirement to elect species within Inventions I and II is improper.

Second, each of the independent claims within Inventions I and II is a generic claim.

“[M]ore than one species of an invention...may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 CFR 1.141 (emphasis added). Echoing this section of the Code of Federal Regulations, the definition of a generic claim is set forth at MPEP 806.04(d):

In general, a generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered in each of the species. For the purpose of obtaining claims to more than one species in the same case, the generic claim cannot include limitations not present in each of the added species claims. Otherwise stated, the claims to the species which can be included in a case in addition to a single species must contain all of the limitations of the generic claim. (emphasis added).

That is, claims reading on multiple species can depend from a single independent generic claim, because a dependent claim serves to limit the independent claim from which it depends, either by further limiting one or more elements or steps of that independent claim, or by adding one or more elements or steps to that independent claim.

With these legal standards in mind, each independent claim will be analyzed in turn. Applicants do not admit that the species identified in the Office Action are indeed species at all, but treat them below as if they are for the purposes of this analysis.

Only four independent claims are present in the application. Claim 1 recites:

1. A method for grafting a graft vessel to a target vessel during an anastomosis procedure, the method comprising:

forming an incision in the target vessel;

placing incision tensioners within the incision in the target vessel;

tensioning the incision in the target vessel with the incision tensioners; and

grafting the graft vessel to the target vessel while the incision is tensioned.

This is the first of two independent claims of Invention I. This is a method claim.

However, it includes the structural limitation of “incision tensioners,” which are structures utilized in performing three of the four claimed steps. The incision tensioners are simply structures useful for holding an incision in tension. Indeed, the specification clearly states that “the incision tensioners may be any device suitable for pulling an incision taut.”

(emphasis added) (page 10, lines 11-12). “The incision tensioners may include any structure suitable for providing tension to an incision, including the previously described anvil, hooks, pins, balloons and clips.” (emphasis added) (page 20, lines 10-12). Those exemplary structures, which are clearly specific instances of the generic incision tensioner structures, are among the species identified in the Office Action. That is, the individual species identified by the Examiner are merely additional limitations of the incision tensioner element added in dependent claims, or additional items added to the generic independent claim.

Claim 2 depends from claim 1, and recites:

2. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners are pins.

The pins are shown in Figures 4A-4B (identified in the Office Action as “Species I”) and described in the specification at page 13, lines 4-21. These “pins 208a are inserted in the

incision to tension the incision 204.” (page 13, line 5). Dependent claim 2 further limits independent claim 1, by limiting the incision tensioners to being pins. Thus, claim 1 is a generic claim, because it includes no material element additional to those recited in species claim 2 and species claim 2 contains all of the limitations of generic claim 1.

Claim 3 depends from claim 1, and recites:

3. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners are hooks.

The hooks are shown in Figures 3A-3B (identified in the Office Action as “Species II”) and described in the specification at page 10, line 21 through page 13, line 1. The hooks are also shown in Figures 8-10B (where Figure 8 is identified in the Office Action as “Species VI”) and described in the specification at page 15, line 13 through page 17, line 7. The “hooks 206a are configured to engage the ends of the incision 204 such that the hooks 206a pull the incision 204 taut.” (page 11, lines 11-12). Dependent claim 3 further limits independent claim 1, by limiting the incision tensioners to being hooks. Thus, claim 1 is a generic claim, because it includes no material element additional to those recited in species claim 3 and species claim 3 contains all of the limitations of generic claim 1.

Claim 4 depends from claim 1, and recites:

4. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners include a cutting surface configured to form the incision within the target vessel.

The cutting surface is shown in Figures 8-10B (where Figure 8 is identified in the Office Action as “Species VI”) and described in the specification at page 15, line 13 through page 17, line 7. The cutting surface is an additional element added to at least one incision tensioner, where the “cutting surface 206a’-2 is configured to form an incision in the target vessel 202.” (page 15, lines 19-21). Dependent claim 4 further limits claim 1, by adding an additional element to the incision tensioners. Thus, claim 1 is a generic claim, because it

includes no material element additional to those recited in species claim 4 and species claim 4 contains all of the limitations of generic claim 1.

Claim 5 depends from claim 1, and recites:

5. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners are sutures.

The sutures are shown in Figures 5A-5B (identified in the Office Action as “Species III”) and described in the specification at page 13, line 22 through page 14, line 14. The “sutures 210a pull the incision 204 taut in order to tension the incision 204.” (page 14, lines 3-4). Dependent claim 5 further limits independent claim 1, by limiting the incision tensioners to being sutures. Thus, claim 1 is a generic claim, because it includes no material element additional to those recited in species claim 5 and species claim 5 contains all of the limitations of generic claim 1.

Claim 6 depends from claim 1, and recites:

6. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners each include a balloon assembly configured to provide tension on the incision in the target vessel.

The balloon assemblies are shown in Figures 6A-6B (identified in the Office Action as “Species IV”) and described in the specification at page 14, line 15 through page 15, line 4. “Upon inflation, the balloon assemblies 212 are used to tension the incision 204.” (page 14, lines 22-23). Dependent claim 6 further limits independent claim 1, by limiting the incision tensioners to include balloon assemblies. Thus, claim 1 is a generic claim, because it includes no material element additional to those recited in species claim 6 and species claim 6 contains all of the limitations of generic claim 1.

Claim 7 depends from claim 6, claim 8 depends from claim 7, and claim 9 depends from claim 8. All of these claims further limit the balloon assemblies of claim 6, and thereby fall into Species IV as identified in the Office Action. Claim 1 includes no material element

additional to those recited in species claims 7-9, and species claims 7-9 each contain all of the limitations of generic claim 1.

Claim 10 depends from claim 1, and recites:

10. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision is tensioned to a predetermined length which corresponds to a size of the graft vessel to be grafted to the target vessel during the anastomosis procedure.

Claim 10 is a method limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the length of the incision in the target vessel, not particular structure for tensioning the incision to that length. Thus, claim 10 reads on every identified species. However, dependent claim 10 does further limit independent claim 1, by restricting the length of the incision relative to the graft vessel. Thus, claim 1 includes no material element additional to those recited in claim 10, and claim 10 contains all of the limitations of generic claim 1. As a result, claim 10 is a proper dependent claim to generic claim 1.

Claim 11 depends from claim 1, and recites:

11. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the operation of tensioning the incision in the target vessel further comprises:

pulling the incision tensioners with a predetermined force.

Claim 11 is a method limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the force with which the incision tensioners are pulled. Thus, claim 11 reads on every identified species. However, dependent claim 11 does further limit independent claim 1, by restricting the length of the incision relative to the graft vessel. Thus, claim 1 includes no material element additional to those recited in claim 11, and claim 11 contains all of the limitations of generic claim 1. As a result, claim 11 is a proper dependent claim to generic claim 1.

Claim 12 depends from claim 11, and further limits the force of claim 11 to a range of between 0.001 N and 4.5 N. Claim 12 includes no material element additional to those recited in generic claim 1, and claim 12 contains all of the limitations of generic claim 1.

Claim 13 depends from claim 1, and recites:

13. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioners are clips which include a first tine and a second tine.

The clips are shown in Figures 11-13 (identified in the Office Action as “Species VII”) and described in the specification at page 17, line 8 through page 18, line 10. “The incision tensioning clips 218 tension the incision 204.” (page 17, lines 16-17). Dependent claim 13 further limits independent claim 1, by limiting the incision tensioners to being clips. Thus, claim 1 is a generic claim, because it includes no material element additional to those recited in species claim 13 and claim 13 contains all of the limitations of generic claim 1.

Claim 14 depends from claim 13, and claims 15 and 16 depend from claim 14. All of these claims further limit the clips of claim 13. Claim 1 includes no material element additional to those recited in claims 14-16, and claims 14-16 each contain all of the limitations of generic claim 1.

Claim 17 depends from claim 1, and recites:

17. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the incision tensioner is an anvil configured to tension the incision in the target vessel.

The anvil is shown in Figures 7A-7B (identified in the Office Action as “Species V”) and described in the specification at page 15, lines 5-12. “[T]he anvil 214a...is configured for insertion in the incision 204 in order to tension the incision 204.” (page 15, lines 9-11). Dependent claim 17 further limits independent claim 1, by limiting the incision tensioners to being an anvil. Thus, claim 1 is a generic claim, because it includes no material element

additional to those recited in species claim 17 and claim 17 contains all of the limitations of generic claim 1.

Claim 18 depends from claim 1, and recites:

18. A method for grafting a graft vessel to a target vessel as recited in claim 1, wherein the tensioning of the incision allows a geometry of the incision in the target vessel to remain constant during the anastomosis procedure.

Claim 18 is a method limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the geometry of the incision that results from its tensioning. Thus, claim 18 reads on every identified species. However, dependent claim 18 does further limit independent claim 1, by restricting the geometry of the incision. Thus, claim 1 includes no material element additional to those recited in claim 18, and claim 18 contains all of the limitations of generic claim 1. As a result, claim 18 is a proper dependent claim to generic claim 1.

Thus, claim 1 is generic to all of the claimed species of claims 2-18 because it includes no material element additional to those recited in species claims 2-18, and species claims 2-18 contain all of the limitations of generic claim 1. Species claims 2-18 are all dependent from claim 1. “[M]ore than one species of an invention...may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 CFR 1.141 (emphasis added). Thus, because claims 2-18 to the species of Invention I are dependent from generic claim 1, the requirement to elect one of those species is improper and should be withdrawn.

Turning to the next independent claim, claim 19 recites:

19. A method for forming an incision in a target vessel for an anastomosis procedure, the method comprising:

inserting a first incision tensioner and a second incision tensioner through a wall of the target vessel; and

separating the first incision tensioner from the second incision tensioner to tension an incision in the target vessel.

This is the second of two independent claims of Invention I. This is a method claim. However, it includes the structural limitations of a “first incision tensioner” and a “second incision tensioner,” which are structures utilized in performing both claimed steps. The incision tensioners are simply structures useful for holding an incision in tension. Indeed, the specification clearly states that “the incision tensioners may be any device suitable for pulling an incision taut.” (emphasis added) (page 10, lines 11-12). “The incision tensioners may include any structure suitable for providing tension to an incision, including the previously described anvil, hooks, pins, balloons and clips.” (emphasis added) (page 20, lines 10-12). Those exemplary structures, which are clearly specific instances of the generic incision tensioner structures, are among the species identified in the Office Action. That is, the individual species identified by the Examiner are merely additional limitations of the incision tensioner element added in dependent claims, or additional items added to the generic independent claim.

Claim 20 depends from claim 19, and recites:

20. A method for forming an incision in a target vessel as recited in claim 19, wherein the incision tensioners remain in the incision in the target vessel during the anastomosis procedure to maintain a known geometry of the incision.

Claim 20 is a method limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the positioning of the incision tensioners relative to the incision in the target vessel during the anastomosis procedure. Thus, claim 20 reads on every identified species. However, dependent claim 20 does further limit independent claim 19, by restricting the position of the incision tensioners during the

anastomosis procedure. Thus, claim 19 includes no material element additional to those recited in claim 20, and claim 20 contains all of the limitations of generic claim 19. As a result, claim 20 is a proper dependent claim to generic claim 19.

Claim 21 depends from claim 20, and further limits the method of claim 20. Claim 19 includes no material element additional to those recited in claim 21, and claim 21 contains all of the limitations of generic claim 19.

Claim 22 depends from claim 19, and recites:

22. A method for forming an incision in a target vessel as recited in Claim 19, wherein the second incision tensioner includes a cutting surface configured to form the incision in the target vessel.

The cutting surface is shown in Figures 8-10B (where Figure 8 is identified in the Office Action as “Species VI”) and described in the specification at page 15, line 13 through page 17, line 7. The cutting surface is an additional element added to at least one incision tensioner, where the “cutting surface 206a’-2 is configured to form an incision in the target vessel 202.” (page 15, lines 19-21). Dependent claim 22 further limits claim 19, by adding an additional element to the incision tensioners. Thus, claim 19 is a generic claim, because it includes no material element additional to those recited in species claim 22 and claim 22 contains all of the limitations of generic claim 19.

Claim 23 depends from claim 19, and recites:

23. A method for forming an incision in a target vessel as recited in Claim 19, wherein the incision tensioners are pins.

The pins are shown in Figures 4A-4B (identified in the Office Action as “Species I”) and described in the specification at page 13, lines 4-21. These “pins 208a are inserted in the incision to tension the incision 204.” (page 13, line 5). Dependent claim 23 further limits independent claim 19, by limiting the incision tensioners to being pins. Thus, claim 19 is a

generic claim, because it includes no material element additional to those recited in species claim 23 and claim 23 contains all of the limitations of generic claim 19.

Claim 24 depends from claim 19, and recites:

24. A method for forming an incision in a target vessel as recited in Claim 19, wherein the incision tensioners are hooks.

The hooks are shown in Figures 3A-3B (identified in the Office Action as “Species II”) and described in the specification at page 10, line 21 through page 13, line 1. The hooks are also shown in Figures 8-10B (where Figure 8 is identified in the Office Action as “Species VI”) and described in the specification at page 15, line 13 through page 17, line 7. The “hooks 206a are configured to engage the ends of the incision 204 such that the hooks 206a pull the incision 204 taut.” (page 11, lines 11-12). Dependent claim 24 further limits independent claim 19, by limiting the incision tensioners to being hooks. Thus, claim 19 is a generic claim, because it includes no material element additional to those recited in species claim 24 and claim 24 contains all of the limitations of generic claim 19.

Claim 25 depends from claim 19, and recites:

25. A method for forming an incision in a target vessel as recited in Claim 19, wherein the incision tensioners form an incision having a predetermined length which corresponds to a size of a graft vessel to be grafted to the target vessel during the anastomosis procedure.

Claim 25 is a method limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the length of the incision in the target vessel, not particular structure for tensioning the incision to that length. Thus, claim 25 reads on every identified species. However, dependent claim 25 does further limit independent claim 19, by restricting the length of the incision relative to the graft vessel. Thus, claim 19 includes no material element additional to those recited in claim 25, and claim 25 contains all of the limitations of generic claim 19.

Thus, claim 19 is generic to all of the claimed species of claims 20-25 because it includes no material element additional to those recited in species claims 20-25, and species claims 20-25 contain all of the limitations of generic claim 19. Species claims 20-25 are all dependent from claim 19. “[M]ore than one species of an invention...may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 CFR 1.141 (emphasis added). Thus, because claims 20-25 to the species of Invention I are dependent from generic claim 19, the requirement to elect one of those species is improper and should be withdrawn.

Turning to the next independent claim, claim 26 recites:

26. A system for aligning a graft vessel to a target vessel having an incision formed therein, the system comprising:

first and second incision tensioners configured for placement within the incision of the target vessel, where the incision tensioners are configured to tension the incision to a predetermined length having a known geometry;

a tensioning device body connected to the incision tensioners;
and

a tensioning mechanism for moving the first incision tensioner with respect to the second incision tensioner.

This is the only independent claim of Invention II. Claim 26 is a system claim that includes several structural limitations, including “first and second incision tensioners.” As discussed above, the incision tensioners are simply structures useful for holding an incision in tension. Indeed, the specification clearly states that “the incision tensioners may be any device suitable for pulling an incision taut.” (emphasis added) (page 10, lines 11-12). “The incision tensioners may include any structure suitable for providing tension to an incision, including the previously described anvil, hooks, pins, balloons and clips.” (emphasis added) (page 20, lines 10-12). Those exemplary structures, which are clearly specific instances of the

generic incision tensioner structures, are among the species identified in the Office Action. That is, the individual species identified by the Examiner are merely additional limitations of the incision tensioner element added in dependent claims, or additional items added to the generic independent claim.

Claim 27 depends from claim 26, and recites:

27. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the tensioning mechanism includes a tension spring for moving the first incision tensioner with respect to the second incision tensioner.

Claim 27 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 27 limits the tensioning mechanism to being a tensioning spring. "The spring 230 may be any spring 230 for separating the tensioner 228 from the tensioner 226." (page 19, lines 9-10). The spring 230 is one of a number of possible tensioning mechanisms for separating the incision tensioners, another example being a torque-applying DC motor. (page 19, lines 13-15). Dependent claim 27 further limits independent claim 26, by limiting the tensioning mechanism to being a spring. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in claim 27 and claim 27 contains all of the limitations of generic claim 26.

Claim 28 depends from claim 26, and recites:

28. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the tensioning mechanism includes a threaded assembly for moving the first incision tensioner with respect to the second incision tensioner.

Claim 28 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 28 limits the tensioning mechanism to being a threaded assembly. The tensioning mechanism can be "a threaded fastener" that "provides a tensioning force." (page 11, lines 4-8). This threaded fastener is one of a number of possible tensioning mechanisms for separating the incision tensioners. Dependent claim 28 further

limits independent claim 26, by limiting the tensioning mechanism to being a threaded assembly. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in claim 28 and claim 28 contains all of the limitations of generic claim 26.

Claim 29 depends from claim 26, and recites:

29. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners are configured to form the incision of the target vessel.

Claim 29 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 29 limits the incision tensioners to a configuration in which at least one of them forms the incision in the target vessel. One way that the incision tensioners can be configured to form the incision of the target vessel is to provide a cutting surface on at least one incision tensioner. Claim 30 further limits dependent claim 29 to include a cutting surface on the first incision tensioner. The cutting surface is shown in Figures 8-10B (where Figure 8 is identified in the Office Action as "Species VI") and described in the specification at page 15, line 13 through page 17, line 7. The cutting surface is an additional element added to at least one incision tensioner, where the "cutting surface 206a'-2 is configured to form an incision in the target vessel 202." (page 15, lines 19-21). Dependent claims 29 and 30 further limit claim 26, by adding an additional element to the incision tensioners. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claims 29 and 30 and claims 29 and 30 each contain all of the limitations of generic claim 26.

Claim 31 depends from claim 26, and recites:

31. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the predetermined length corresponds to a size of the graft vessel to be grafted to the target vessel during the anastomosis procedure.

Claim 31 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 31 limits the length of the incision in the target vessel, not particular structure for tensioning the incision to that length. Thus, claim 31 reads on every identified species. However, dependent claim 31 does further limit independent claim 26, by restricting the length of the incision relative to the graft vessel. Thus, claim 26 includes no material element additional to those recited in claim 31, and claim 31 contains all of the limitations of generic claim 26. As a result, claim 31 is a proper dependent claim to generic claim 26.

Claim 32 depends from claim 26, and recites:

32. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners are hooks.

The hooks are shown in Figures 3A-3B (identified in the Office Action as “Species II”) and described in the specification at page 10, line 21 through page 13, line 1. The hooks are also shown in Figures 8-10B (where Figure 8 is identified in the Office Action as “Species VI”) and described in the specification at page 15, line 13 through page 17, line 7. The “hooks 206a are configured to engage the ends of the incision 204 such that the hooks 206a pull the incision 204 taut.” (page 11, lines 11-12). Dependent claim 32 further limits independent claim 26, by limiting the incision tensioners to being hooks. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claim 32 and claim 32 contains all of the limitations of generic claim 26.

Claim 33 depends from claim 26, and recites:

33. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners are pins.

The pins are shown in Figures 4A-4B (identified in the Office Action as “Species I”) and described in the specification at page 13, lines 4-21. These “pins 208a are inserted in the incision to tension the incision 204.” (page 13, line 5). Dependent claim 33 further limits

independent claim 26, by limiting the incision tensioners to being pins. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claim 33 and claim 33 contains all of the limitations of generic claim 26.

Claim 34 depends from claim 26, and recites:

34. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners are sutures.

The sutures are shown in Figures 5A-5B (identified in the Office Action as “Species III”) and described in the specification at page 13, line 22 through page 14, line 14. The “sutures 210a pull the incision 204 taut in order to tension the incision 204.” (page 14, lines 3-4). Dependent claim 34 further limits independent claim 26, by limiting the incision tensioners to being sutures. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claim 34 and claim 34 contains all of the limitations of generic claim 26.

Claim 35 depends from claim 26, and recites:

35. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners each include a balloon assembly configured to tension the incision of the target vessel.

The balloon assemblies are shown in Figures 6A-6B (identified in the Office Action as “Species IV”) and described in the specification at page 14, line 15 through page 15, line 4. “Upon inflation, the balloon assemblies 212 are used to tension the incision 204.” (page 14, lines 22-23). Dependent claim 35 further limits independent claim 1, by limiting the incision tensioners to include balloon assemblies. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claim 35 and claim 35 contains all of the limitations of generic claim 26.

Claim 36 depends from claim 35, claim 37 depends from claim 36, claim 38 depends from claim 37, and claim 39 depends from claim 38. All of these claims further limit the

balloon assemblies of claim 35 or the operation thereof, and thereby fall into Species IV as identified in the Office Action. Claim 26 includes no material element additional to those recited in species claims 36-39, and claims 36-39 each contain all of the limitations of generic claim 26.

Claim 40 depends from claim 26, and recites:

40. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the tensioning mechanism moves the first incision tensioner with respect to the second incision tensioner using a predetermined force.

Claim 40 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns the force with which the incision tensioners are pulled. Thus, claim 40 reads on every identified species. However, dependent claim 40 does further limit independent claim 26, by restricting the length of the incision relative to the graft vessel. Thus, claim 26 includes no material element additional to those recited in claim 40, and claim 40 contains all of the limitations of generic claim 26. As a result, claim 40 is a proper dependent claim to generic claim 26.

Claim 41 depends from claim 40, and further limits the force of claim 40 to a range of between 0.001 N and 4.5 N. Claim 41 includes no material element additional to those recited in claim 26, and claim 41 contains all of the limitations of generic claim 26.

Claim 42 depends from claim 26, and recites:

42. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners are incision tensioner clips which includes [sic] a first tine and a second tine.

The clips are shown in Figures 11-13 (identified in the Office Action as “Species VII”) and described in the specification at page 17, line 8 through page 18, line 10. “The incision tensioning clips 218 tension the incision 204.” (page 17, lines 16-17). Dependent claim 42 further limits independent claim 26, by limiting the incision tensioners to being

clips. Thus, claim 26 is a generic claim, because it includes no material element additional to those recited in species claim 42 and claim 42 contains all of the limitations of generic claim 26.

Claim 43 depends from claim 42, and claims 44 and 45 depend from claim 43. All of these claims further limit the clips of claim 42. Claim 26 includes no material element additional to those recited in claims 43-45, and claims 43-45 each contain all of the limitations of generic claim 26.

Claim 46 depends from claim 26, and recites:

46. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the incision tensioners maintain the known geometry of the incision during an anastomosis procedure.

Claim 46 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns maintaining the geometry of the incision. Thus, claim 46 reads on every identified species. However, dependent claim 46 does further limit independent claim 26, by restricting the geometry of the incision. Thus, claim 26 includes no material element additional to those recited in claim 46, and claim 46 contains all of the limitations of generic claim 26.. As a result, claim 46 is a proper dependent claim to generic claim 26.

Claim 47 depends from claim 26, and recites:

47. A system for aligning a graft vessel to a target vessel as recited in Claim 26, wherein the known geometry allows the incision in the target to [sic] vessel to remain constant during the anastomosis procedure.

Claim 47 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns allowing the known geometry of the incision to remain constant. Thus, claim 47 reads on every identified species. However, dependent claim 47 does further limit independent claim 26, by restricting the geometry of the

incision. Thus, claim 26 includes no material element additional to those recited in claim 47, and claim 47 contains all of the limitations of generic claim 26. As a result, claim 46 is a proper dependent claim to generic claim 26.

Thus, claim 26 is generic to all of the claimed species of claims 27-47 because it includes no material element additional to those recited in species claims 27-47, and species claims 27-47 contain all of the limitations of generic claim 26. Claims 27-47 are all dependent from claim 26. “[M]ore than one species of an invention...may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 CFR 1.141 (emphasis added). Thus, because claims 27-47 to the species of Invention II are dependent from generic claim 26, the requirement to elect one of those species is improper and should be withdrawn.

Finally, independent claim 48 recites:

48. A tension control device for aligning a graft vessel to a target vessel having an incision formed therein during an anastomosis procedure, the tension control device comprising a first tensioner slidably coupled with a second tensioner, where the tensioners are configured to tension the incision formed in the target vessel with a predetermined force imparted to the tensioners with a force applying mechanism.

This is the only independent claim of Invention III. Claim 48 is a device claim that includes several structural limitations, including a “first tensioner,” which is “slidably coupled” with a “second tensioner.” As discussed above, the incision tensioners are simply structures useful for holding an incision in tension. Indeed, the specification clearly states that “the incision tensioners may be any device suitable for pulling an incision taut.” (emphasis added) (page 10, lines 11-12). “The incision tensioners may include any structure suitable for providing tension to an incision, including the previously described anvil, hooks, pins, balloons and clips.” (emphasis added) (page 20, lines 10-12). Those exemplary

structures, which are clearly specific instances of the generic incision tensioner structures, are among the species identified in the Office Action. That is, the individual species identified by the Examiner are merely additional limitations of the incision tensioner element added in dependent claims, or additional items added to the generic independent claim.

Claim 49 depends from claim 48, and recites:

49. A tension control device as recited in claim 48, wherein the tension control device forms the incision in the target vessel to a known geometry.

Claim 49 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. That is, it concerns maintaining the geometry of the incision. Thus, claim 49 reads on every identified species. However, dependent claim 49 does further limit independent claim 48, by restricting the geometry of the incision. Thus, claim 48 includes no material element additional to those recited in claim 49, and claim 49 contains all of the limitations of generic claim 48. As a result, claim 49 is a proper dependent claim to generic claim 48.

Claim 50 depends from claim 49, and further limits the geometry of the incision.

Claim 48 includes no material element additional to those recited in claim 50, and claim 50 contains all of the limitations of generic claim 48.

Claim 51 depends from claim 48, and recites:

51. A tension control device as recited in claim 48, wherein the force applying mechanism is a spring.

Claim 51 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 51 limits the force applying mechanism to being a tensioning spring. The “spring 230 imparts a force on the tensioner 228 in order to separate the tensioner 228 from the tensioner 226.” (page 19, lines 6-7). “The spring 230 may be any spring 230 for separating the tensioner 228 from the tensioner 226.” (page 19,

lines 9-10). The spring 230 is one of a number of possible tensioning mechanisms for separating the incision tensioners, another example being a torque-applying DC motor. (page 19, lines 13-15). Thus, dependent claim 51 further limits independent claim 48, by limiting the tensioning mechanism to being a spring. Claim 48 is a generic claim because it includes no material element additional to those recited in claim 51, and claim 51 contains all of the limitations of generic claim 48.

Claim 52 depends from claim 48, and recites:

52. A tension control device as recited in claim 48, wherein the first tensioner couples with the second tensioner using a notch.

Claim 52 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 52 limits the force applying mechanism to being a tensioning spring. The notch is a structure that allows the tensioners to slide relative to one another. "The notch 228c is configured such that the tensioner 228 slidably attaches to the tensioner 226." (page 19, lines 4-5). The notch is one possible structure for coupling the tensioners together. Thus, dependent claim 52 further limits independent claim 48, by limiting the tensioning mechanism to being a spring. Claim 48 is a generic claim because it includes no material element additional to those recited in claim 52, and claim 52 contains all of the limitations of generic claim 48.

Claim 53 depends from claim 48, and recites:

53. A tension control device as recited in claim 48, wherein the first tensioner and the second tensioner include removable portions in order to facilitate grafting of the graft vessel to the target vessel during the anastomosis procedure.

Claim 53 is a structural limitation that is not uniquely associated with any of the species identified in the Office Action. Claim 53 limits the tensioners to having removable portions. The "graft vessel 220 is placed over the removable sections 226b and 228b. The removable sections 226b and 228b are then removed in order to allow grafting of the graft

vessel 220 to the target vessel 202.” (page 20, lines 1-4). The removable portions are optional components of the tensioners. Thus, dependent claim 53 further limits independent claim 48, by limiting the tensioners to having removable portions. Claim 48 is a generic claim because it includes no material element additional to those recited in claim 53, and claim 53 contains all of the limitations of generic claim 48.

Thus, claim 48 is generic to all of the claimed species of claims 49-53 because it includes no material element additional to those recited in species claims 49-53, and species claims 49-53 contain all of the limitations of generic claim 48. Claims 49-53 are all dependent from claim 48. “[M]ore than one species of an invention...may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form.” 37 CFR 1.141 (emphasis added). Thus, because claims 49-53 to the species of Invention III are dependent from generic claim 48, the requirement to elect one of those species is improper and should be withdrawn.

**REQUEST FOR RECONSIDERATION OF REQUIREMENT TO ELECT SPECIES,
OR IN THE ALTERNATIVE FOR A FINAL REQUIREMENT FOR RESTRICTION**

Applicants have distinctly and specifically pointed out the errors in the restriction requirement in order to elect with traverse and preserve the right to petition the Commissioner to review the restriction requirement.

Applicants request that the requirement to elect species with regard to Invention I be reconsidered and withdrawn, for the reasons set forth above. In the alternative, Applicants

request a final requirement for election of species under 37 CFR 1.144, so that Applicants may petition the Commissioner for a withdrawal of that requirement.

VIA EXPRESS MAIL
EV167837076US

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 326-5600 x162
Chief Patent Counsel
Cardica, Inc.
Customer No. 33109